



Food and Drug Administration
10903 New Hampshire Avenue
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August 21, 2014

OrthoHelix Surgical Designs, Inc.
Mr. Brian Hockett
Director of Engineering – Lower Extremity
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K142148
Trade/Device Name: OrthoHelix™ Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: July 16, 2014
Received: August 7, 2014

Dear Mr. Brian Hockett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142148

Device Name: OrthoHelix™ Staple System

Indications for Use:

The OrthoHelix™ Staple System is indicated for fixation in the hand and foot including fractures, fusions, and osteotomies.

Prescription Use X

AND/OR

Over-The-Counter-Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY**Submitter Information**

Submitter's Name: OrthoHelix Surgical Designs, Inc.
 Address: 1065 Medina Rd, Suite 500
 Medina, Ohio 44256
 Telephone Number: 330-869-9562
 Fax Number: 330-247-1598
 Prepared By: Liz Altenau
 Contact Person: Brian Hockett or Liz Altenau
 Date Prepared: 7/16/14

Device Information

Trade Name: OrthoHelix™ Staple System

Common Name: Bone Staple

Classification Name: Staple, Fixation, Bone

Device Classification: Single/multiple component metallic bone fixation appliances and accessories
 Class II per 21 CFR 888.3030
 Panel: Orthopedic, Product Code: JDR

Material Composition: Nickel Titanium Alloy

Device Description: The OrthoHelix™ Staple System consists of various sizes of staples used for fixation in the hand and foot. The staples are offered in different lengths, widths, and thicknesses. All implantable devices within this system are manufactured from shape memory nickel titanium alloy.

Intended Use: The OrthoHelix™ Staple System is indicated for fixation in the hand and foot including fractures, fusions, and osteotomies.

Substantial Equivalence: The new OrthoHelix staples are substantially equivalent to the existing OrthoHelix Staple System (K130832), the Stryker (Memometal Technologies) EasyClip Staple (K070031), and the BioMedical Enterprises Inc. Speed Staple (K993714). This submission is a modification to the OrthoHelix Staple System to add new staple sizes. The OrthoHelix Staple System conforms to ASTM F2063 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. Engineering calculations, finite element analysis, mechanical bending and pullout tests per ASTM F564, and corrosion testing per ASTM F2129 were performed to demonstrate substantial equivalence of the subject to the predicate devices. No new issues of safety and effectiveness have been raised.